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PATENT DOCKET NUMBER P41 9755

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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SUPPLEMENTAL COMMUNICATION RE: REQUEST TO DECLARE INTERFERENCE WITH U.S. PATENT NO. 5,428,071

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

This Communication is being submitted to further develop issues addressed at the July 26, 1995 personal interview of this application. At the interview, a potential interference between claims 51-53 of the above-identified application and U.S. Patent No. 5,428,071 issued to Bollag et al. was discussed. During that interview, the potential application of 35 U.S.C. §112 paragraphs 1 and 2 was discussed, particularly with reference to newly submitted claims 51-53.

With respect to Section 112, paragraph 2, it is respectfully submitted that claims 51-53 are sufficiently definite as they are substantially the same as claims 1, 7 and 14 of issued U.S. Patent No. 5,428,071.

With respect to the written description requirement of Section 112, paragraph 1, submitted herewith is an executed declaration of Robert B. Stein, M.D., Ph.D (the fully

executed copy of this declaration will be submitted under separate cover), asserting that the disclosure of the parent of the above-identified application, i.e., U.S. Patent Application Serial No. 07/809,980 ("the '980 application"), clearly describes to one of ordinary skill in the art the subject matter now presented in claims 51-53.

It is well established that the written description requirement of Section 112 is directed to one of ordinary skill in the art. <u>In re Hayes Microcomputer Products Patent Lit.</u>, 25 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1992). The standard for assessing compliance with the written description requirement has been stated as follows:

Although [the applicant] does not have to describe exactly the subject matter claimed, ... the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed ... the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

(Citations omitted.)

Vas-Cath, Inc. v. Mahurkar, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991).

The declaration of Dr. Robert B. Stein is submitted to establish that the '980 application discloses the treatment and prevention of cancers of epithelial origin (*i.e.*, carcinomas) with 9-*cis* retinoic acid as required by claims 51-53. Although the term "epithelial" is not specifically used in the '980 application, the disclosure of prevention and treatment of lung cancer and testicular cancer with 9-cis retinoic acid in the '980 application reasonably conveys to one skilled in the art that the applicants had contemplated and disclosed the prevention and treatment of cancers of epithelial origin (*i.e.*, carcinomas) with 9-*cis* retinoic acid. Stein Decl. ¶¶ 3-5. Thus, the absence of the word "epithelial" from the '980 application does not support a rejection under the written description requirement. See e.g., In re Smith, 178 U.S.P.Q. 620, 624 (C.C.P.A. 1973) ("This court has held that claimed subject matter need not be described in haec verba in the specification in order for that specification to satisfy the description requirement . . ."); Heymes v. Takaya, 6 U.S.P.Q. 2d 1448, 1452 (BPAI 1988)) ("It is not necessary that

the claimed subject matter be described in <u>ipsis verbis</u> to satisfy the written description requirement of 35 U.S.C. §112 ... The issue is whether the Takaya specification conveys clearly to those skilled in the art that Takaya invented the compounds at issue.").

Further, in the context of an interference, it is recognized that the disclosure of a species alone is sufficient to support a generic claim. E.g., Utter v. Hiraga, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988) ("Utter says Hiraga was not entitled to make the generic '068 count because he disclosed only one of the '069 and '071 species it encompassed ... A specification may, within the meaning of 35 U.S.C. §112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses."); Suh v. Hoefle, 23 U.S.P.Q. 2d 1321, 1325 (BPAI 1991).

As plainly set forth in the Stein declaration, applicants have disclosed two types of cancer (lung and testicular) derived from tissues of epithelial origin. Based upon this disclosure, one of ordinary skill in the art would readily recognize that the applicants had invented the subject matter of claims 51-53 at the time the '980 application was filed. Thus, the '980 application fully supports claims 51-53 in light of 35 U.S.C. §112, ¶ 1.

It is respectfully submitted that presentation of this Supplemental Communication and the Declaration of Robert B. Stein, M.D., Ph.D., along with the previous Communication and Supplemental Preliminary Amendment filed in the above-identified application, place the claims of the present application in condition for allowance, and accordingly for a declaration of interference with U.S. Patent No. 5,428,071. Notification to that effect is earnestly solicited.

Respectfully submitted,

Date: $\frac{8}{10}$ 95

Stephen E. Reiter

Registration No. 31,192

Telephone: (619) 546-1995 Facsimile: (619) 546-9392

PRETTY, SCHROEDER
BRUEGGEMANN & CLARK
444 South Flower Street, Suite 2000
Los Angeles, California 90071

Enclosure: Declaration of Dr. Robert B. Stein

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The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 16-2460. A duplicate copy of this

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